UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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WILLIAM JEFFERSON and CHARMAYNE JEFFERSON,

Plaintiffs,

– Against –

OLYMPUS AMERICA INC., OLYMPUS CORPORATION OF THE AMERICAS, OLYMPUS MEDICAL SYSTEMS CORPORATION, and OLYMPUS CORPORATION

Defendants.

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COMPLAINT AND JURY DEMAND

CIVIL ACTION NO.

Plaintiffs, by their attorneys, **DOUGLAS & LONDON, P.C.**, upon information and belief, at all times hereinafter mentioned, allege as follows:

NATURE OF THE CASE

1. This action is brought on behalf of Plaintiff, WILLIAM JEFFERSON, who underwent an endoscopic retrograde cholangiopancreatography (hereinafter referred to as "ERCP") procedure in which a defective Olympus TJF-Q180V Duodenoscope (hereinafter referred to as "Q180V Scope") was used.

2. At all relevant times, Defendants OLYMPUS AMERICA INC., OLYMPOUS CORPORATION OF THE AMERICAS, OLYMPUS MEDICAL SYSTEMS CORPORATION, and OLYMPUS CORPORATION (hereinafter collectively referred to as "Defendants") created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Q180V Scope.

3. When warning of the safety, risks and/or defects of the Q180V Scope, Defendants made misrepresentations regarding same and concealed their extensive knowledge of the Q180V Scope's defects from Plaintiff and other patients, the United States Federal Drug Administration ("FDA"), the medical community, and the general public for several years, specifically that the Q180V Scope could cause serious and grave health consequences, including but not limited to the spread of life-threatening infections from one patient to another.

4. The failure on the part of Defendants to make known the dangerous defects of the Q180V Scope to the Plaintiff and/or his treating healthcare providers while continuing to manufacture, advertise, promote, market, sell, and/or distribute the device demonstrated an unlawful and unethical indifference to the welfare and safety of the Plaintiff and other patients.

5. The willfully reckless and/or negligent actions of Defendants caused the Plaintiff to contract a life-threatening infection and, resultantly, to suffer significant pain, discomfort, emotional distress, and a diminished quality of life.

6. Consequently, the Plaintiffs seek redress from Defendants in the form of compensatory and punitive damages, as well as any other damages that the Court or jury may find appropriate.

JURISDICTION

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

8. This Court has personal jurisdiction over this action because, at all relevant times, each and every Defendant transacted business in New York, each and every Defendant committed

certain of the tortious acts complained of herein in new York, and each and every Defendant derived substantial revenue from goods used in New York, including the Q180V Scope and other similar duodenoscopes and medical equipment, such that each and every Defendant should have reasonably expected its acts to have consequences within New York.

PARTY PLAINTIFFS

9. Plaintiff, WILLIAM JEFFERSON, is a citizen of the United States of America and a resident of the State of Washington.

10. Plaintiff, WILLIAM JEFFERSON, was born on November 23, 1959.

11. Plaintiff, WILLIAM JEFFERSON, underwent an ERCP procedure on or about February 23, 2015 at Swedish Medical Center in Seattle, Washington, during which his physician, Dr. John Brandabur, used the Q180V Scope.

12. Due to the conduct of all Defendants as alleged herein and as a result of Defendants' Q180V Scope that was used during the aforementioned ERCP procedure, Plaintiff, WILLIAM JEFFERSON, was caused to suffer a life-threatening infection.

13. The above-stated infection caused Plaintiff, WILLIAM JEFFERSON, to sustain severe personal injuries, pain, suffering, and emotional distress, as well as to incur substantial medical expenses.

14. Plaintiff CHARMAYNE JEFFERSON is a citizen of the United States of America, and is a citizen and resident of the State of Washington, and at all relevant times, was the lawful spouse of Plaintiff William Jefferson.

PARTY DEFENDANTS

15. Defendant OLYMPUS AMERICA INC. (hereafter "OLYMPUS USA") is a corporation organized under the laws of New York, with a principal place of business at 3500 Corporate Parkway, Center Valley, Pennsylvania 18034.

16. Defendant OLYMPUS USA serves as the headquarters for sales, advertising, promoting and marketing of medical products, among other goods and services, of OLYMPUS CORPORATION in the United States.

17. Defendant OLYMPUS USA at all times relevant herein was in the business of creating, designing, researching, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing medical equipment, including but not limited to duodenoscopes and the subject Q180V Scopes, into the stream of commerce for use by the public, including the Plaintiff.

18. Defendant OLYMPUS USA has transacted and conducted business in the States of Washington and New York.

19. Defendant OLYMPUS USA has derived substantial revenue from goods and products used in the States of Washington and New York.

20. Defendant OLYMPUS USA expected or should have expected its acts to have consequences within the States of Washington and New York and derives substantial revenue from interstate commerce within the United States of America, and the States of Washington and New York, more particularly.

21. Upon information and belief, Defendant OLYMPUS CORPORATION OF THE AMERICAS (hereafter "OLYMPUS AMERICAS") is a corporation organized under the laws of

New York, with a principal place of business at 3500 Corporate Parkway, Center Valley, Pennsylvania 18034.

22. OLYMPUS AMERICAS serves as the headquarters for OLYMPUS CORPORATION's operations in the United States, Canada, and Latin America.

23. Defendant OLYMPUS AMERICAS at all times relevant herein was in the business of creating, designing, researching, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing medical equipment, including but not limited to duodenoscopes and the subject Q180V Scopes, into the stream of commerce for use by the public, including the Plaintiff.

24. Defendant OLYMPUS AMERICAS has transacted and conducted business in the States of Washington and New York.

25. Defendant OLYMPUS AMERICAS has derived substantial revenue from goods and products used in the States of Washington and New York.

26. Defendant OLYMPUS AMERICAS expected or should have expected its acts to have consequences within the States of Washington and New York and derives substantial revenue from interstate commerce within the United States of America, and the States of Washington and New York, more particularly.

27. Upon information and belief, Defendant OLYMPUS MEDICAL SYSTEMS CORPORATION (hereafter "OLYMPUS MEDICAL") is a corporation organized under the laws of Japan, with a principal place of business at Shinjuku Monolith, 2-3-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0914, Japan.

28. Defendant OLYMPUS MEDICAL at all times relevant herein was in the business of creating, designing, researching, testing, manufacturing, labeling, advertising, marketing,

promoting, selling and distributing medical equipment, including but not limited to duodenoscopes and the subject Q180V Scopes, into the stream of commerce for use by the public, including the Plaintiff.

29. Defendant OLYMPUS MEDICAL has transacted and conducted business in the States of Washington and New York.

30. Defendant OLYMPUS MEDICAL has derived substantial revenue from goods and products used in the States of Washington and New York.

31. Defendant OLYMPUS MEDICAL expected or should have expected its acts to have consequences within the States of Washington and New York and derives substantial revenue from interstate commerce within the United States of America, and the States of Washington and New York, more particularly.

32. OLYMPUS CORPORATION is a corporation domiciled in Japan, with a principal place of business at Shinjuku Monolith, 2-3-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0914, Japan.

33. OLYMPUS CORPORATION has approximately 70 percent of the global market for all gastrointestinal endoscopes and produces around 85 percent of duodenoscopes used in the United States.

34. Defendant OLYMPUS CORPORATION is the parent corporation of Defendants OLYMPUS USA, OLYMPUS AMERICAS, and OLYMPUS MEDICAL.

35. Defendant OLYMPUS CORPORATION at all times relevant herein was in the business of creating, designing, researching, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing medical equipment, including but not limited to

duodenoscopes and the subject Q180V Scopes, into the stream of commerce for use by the public, including the Plaintiff.

36. Defendant OLYMPUS CORPORATION has transacted and conducted business in the States of Washington and New York.

37. Defendant OLYMPUS CORPORATION has derived substantial revenue from goods and products used in the States of Washington and New York.

38. Defendant OLYMPUS CORPORATION expected or should have expected its acts to have consequences within the States of Washington and New York and derives substantial revenue from interstate commerce within the United States of America, and the States of Washington and New York, more particularly.

39. Each and every Defendant created, designed, researched, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and/or distributed the Q180V Scope for the primary purpose of use in ERCP.

40. At all times mentioned, each Defendant was the representative, agent, employee, joint venturer, or alter ego of each of the other Defendants and in doing the things alleged herein was acting within the scope of its authority as such.

FACTUAL BACKGROUND

41. At all relevant times, each and every Defendant was in the business of and did create, design, research, manufacture, test, advertise, promote, market, label, sell and distribute the Q180V Scope, to be used by medical practitioners for the primary purpose of use in ERCP, an internal and invasive procedure.

42. At all relevant times, Defendants' acts in the creation, design, research, manufacture, testing, advertisement, promotion, marketing, labeling, sale and distribution of the

Q180V Scope for the primary purpose of use in ERCP were negligent, reckless, willful, wanton and/or fraudulent as outlined herein.

43. ERCP is a combination upper endoscopy and X-ray used to examine the pancreatic and bile ducts for the purpose of diagnosing diseases in this area of the body, including the liver, gallbladder, and pancreas, and/or treating a narrowing or blockage of these ducts.

44. The medical instrument used in ERCP, known as a duodenoscope, is a long, flexible endoscope with a camera and light.

45. A duodenoscope is fed through a patient's mouth, throat, and stomach into the duodenum so as to allow the physician to view and/or access the liver, gallbladder, pancreas and bile ducts, among other things.

46. Duodenoscopes are reusable medical devices meaning that they are designed to be reused from patient to patient.

47. All duodenoscope models require reprocessing, which is an intensive multi-step cleaning process, the purpose of which is, among other things, not to spread contaminants between patients.

48. A duodenoscope contains an elevator wire channel that allows the doctor to insert the guidewire and catheter into the patient's duodenum.

49. Where earlier duodenoscope models left the elevator wire channel exposed, newer models, such as Defendants' Q180V Scope, were designed to seal off this channel; these newer models are referred to as "closed-channel" duodenoscopes.

50. Defendants' Q180V Scope was the first "closed-channel" duodenoscope to be marked in the United States beginning in 2010.

51. Each and every Defendant marketed, advertised and/or promoted their "closed-channel" duodenoscopes, including their Q180V Scopes, as superior to other duodenoscopes on the market because of this "closed-channel" design.

52. Each and every Defendant marketed, advertised and/or promoted that their "closed-channel" duodenoscopes, including their Q180V Scopes, prevented the elevator wire channel from exposure to microbial contamination, thereby reducing the risk of the spread of infection.

53. Each and every Defendant marketed, advertised and/or promoted that their "closed-channel" duodenoscopes, including their Q180V Scopes, prevented infectious material from entering the scope, thereby, reducing the risk of the spread of infection.

54. However, at all relevant times, the design and manufacture of the Q180V Scope's elevator channel sealing mechanism, called an "O-ring," was defective and allowed for leakage of contaminants such as patient fluids and tissue into the channel.

55. Additionally, the closed-channel design of the Q180V Scope impeded thorough cleansing and sanitizing of the channel through the reprocessing process.

56. At all relevant times, the design of the Q180V Scope included several crevices too small to clean or sanitize in the standard manner, but large enough to trap microbial contaminants and cause the spread of infection.

57. Upon information and belief, each and every Defendant did not take reasonably adequate steps to test the efficacy of its reprocessing instructions for the Q180V Scope before introducing this instrument into the stream of commerce.

58. The standard reprocessing protocol for duodenoscopes, including the Q180V Scope, involved, at all relevant times, three steps: point-of-use processing (rinsing or wiping the device), thorough cleaning by a technician, and high level disinfection ("HLD").

59. At all relevant times, HLD of the Q180V Scope (and of most other endoscopes) was typically achieved through use of devices called Automated Endoscope Reprocessors ("AERs"), which kill microbes by flushing a chemical solution through the scope.

60. The above reprocessing protocol was explicitly prescribed to healthcare facilities in the Q180V Scope's manufacturer's instructions, though the protocol was insufficient to prevent the spread of infection from patient to patient.

61. The Q180V Scope did not simply fail to protect patients from contamination better than earlier models as marketed by each and every Defendant; rather, its faulty design, which included but is not limited to its faulty reprocessing instructions, put Plaintiff and other patients at an unreasonable increased risk of contracting infection.

62. The FDA was not initially aware of the Q180V Scope's harmful defects because Defendants failed to seek FDA approval for the closed-channel design of the instrument, based on the corporation's self-serving internal determination that it did not significantly differ from its previously approved model, the Q160V Scope.

63. For several years, Defendants also neglected to alert the medical community or the general public of the United States to the mounting evidence indicating that the Q180V Scope was, at all relevant times, unsafe and unfit for use.

64. By May 2012, Defendants were aware that the design of the Q180V Scope was defective and allowed for the retention of microbial contamination after reprocessing in the manner prescribed to healthcare facilities in the manufacturers' instructions.

65. By Autumn of 2012, Defendants knew that the Q180V Scope was linked to outbreaks of dangerous antibiotic-resistant infections in both the United States and Europe.

66. By July 2013, Defendants were aware that its testing data regarding the Q180V Scope's reprocessing instructions was scientifically unsound and insufficient to prove the instructions effective.

67. In January 2016, after the FDA became aware of the defects associated with the Q180V Scope and after the FDA required that each and every Defendant fix the defects as outlined herein, submit a 510(k) application for the Q180V Scope and modify its reprocessing instructions, the FDA cleared a new version of the Q180V Scope with design modifications to the elevator channel to create a tighter seal and reduce the potential for leakage of patient fluids and tissue into the closed elevator channel.

68. Defendants' actions and inactions as set forth herein endangered the health and welfare of countless patients, including Plaintiff, WILLIAM JEFFERSON, and demonstrated each and every Defendant's reckless disregard for each of them.

69. As a result of each and every Defendants' concealment and/or failure to advise and/or warn all doctors and/or his healthcare providers of the defectiveness and/or serious adverse health risks associated with their Q180V Scopes as set forth herein, life-threatening infections were spread from one patient to another patient, such as the Plaintiff WILLIAM JEFFERSON.

70. As a result of the defective nature of the Q180V Scope, which was known and/or should have been known by each and every Defendant at all relevant times, those persons who underwent procedures in which Q180V Scopes were used, including the Plaintiff WILLIAM JEFFERSON, have suffered from, are suffering from and/or will suffer from serious and grave health consequences, including but not limited to life-threatening infections and any and all of their sequelae.

FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENCE)

71. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 70, with the same force and effect as if more fully set forth herein.

72. Defendants' Q180V Scope was expected to, and did, reach the intended physicians and patients, including Plaintiff, WILLIAM JEFFERSON, without substantial change to the condition in which it was designed, manufactured, supplied, promoted, advertised, labeled, sold, and/or distributed by Defendants.

73. Defendants had a duty to exercise reasonable care in the creation, design, research, manufacture, testing, marketing, supply, promotion, advertising, labeling, sale, and/or distribution of the Q180V Scope into the stream of commerce, including but not limited to a duty to assure that the device would not leave patients vulnerable to infection and illness as a result of device contamination.

74. Defendants also had a duty to create, design, manufacture, research, manufacture, test, market, supply, promote, advertise, label, sell, and/or distribute an instrument like the Q180V Scope in such a way as to avoid harm to patients upon whom it was to be used, such as the Plaintiff WILLIAM JEFFERSON, and/or to refrain from such activities upon the knowledge and/or constructive knowledge that such an instrument posed an unreasonable risk of harm to patients upon whom it was to be used, such as the Plaintiff WILLIAM JEFFERSON.

75. Defendants failed to exercise ordinary care in creating, designing, researching, manufacturing, marketing, supplying, promoting, labeling, advertising, packaging, selling, testing, quality assurance, quality control and/or distributing the Q180V Scope into interstate commerce in that Defendants knew or should have known that using the Q180V Scope created a high risk of

unreasonable, dangerous side effects, including severe and personal injuries such as infections, which may be lasting in nature, physical pain and mental anguish, diminished enjoyment of life, the need for lifelong medical treatment, monitoring and/or medications, and fear of infection recurrence.

76. Defendants violated its above-listed duties in myriad ways, including but not limited to the following:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing the Q180V Scope without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing the Q180V Scope without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not the Q180V Scope was safe for use, in that Defendants herein knew or should have known that the Q180V Scope was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling the Q180V Scope without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of the Q180V Scope;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, the Q180V Scope;

(g) Failing to provide adequate instructions regarding the reprocessing of the Q180V Scope to be performed by users, handlers, and persons who would reasonably and foreseeably come into contact with the Q180V Scope;

(h) Failing to test the Q180V Scope and/or failing to adequately, sufficiently and properly test the Q180V Scope;

(i) Negligently promoting, marketing, advertising and/or recommending the use of the Q180V Scope without sufficient knowledge as to its dangerous propensities, including but not limited to increased risk of microbial contamination and the spreading of infection from one patient to another;

(j) Negligently representing that the Q180V Scope was safe for use for its intended purpose, when, in fact, it was unsafe in that it allowed for microbial contamination and the spread of infection from one patient to another;

(k) Negligently designing the Q180V Scope in a manner which was dangerous to its users, such that it allowed for microbial contamination and the spread of infection from one patient to another;

(l) Negligently manufacturing the Q180V Scope in a manner which was dangerous to its users, such that it allowed for microbial contamination and the spread of infection from one patient to another;

(m) Negligently producing the Q180V Scope in a manner which was dangerous to its users, such that it allowed for microbial contamination and the spread of infection from one patient to another;

(n) Negligently assembling the Q180V Scope in a manner which was dangerous to its users, such that it allowed for microbial contamination and the spread of infection from one patient to another;

(o) Concealing information concerning FDA regulations and warnings from the Plaintiff and his healthcare providers in knowing that the Q180V Scope was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of the Q180V Scope;

(q) Failing to respond promptly and adequately to testing indicating that the Q180V Scope was unsafe for use as directed in the manufacturers' instructions and/or reprocessing instructions, such that it allowed for microbial contamination and the spread of infection from one patient to another;

(r) Failing to act promptly to revise the manufacturers' instructions and reprocessing instructions upon learning of their deficiencies;

(s) Failing to promptly adjust the design and manufacture of the Q180V Scope upon learning of its defects;

(t) Manufacturing, marketing, advertising, supplying, promoting, selling, and/or distributing the Q180V Scope given their knowledge of its defects;

(u) Concealing the defects of the Q180V Scope and the deficiencies of its instructions from the Plaintiff, his healthcare providers, the FDA, the medical community, and the general public of the United States; and

(v) Disregarding the safety and welfare of patients, including Plaintiff WILLIAM JEFFERSON, by failing to withdraw the Q180V Scope from the market, revise the device's design, revise the device's reprocessing instructions, and/or otherwise restrict use of the device.

77. Despite the fact that Defendants knew or should have known that the Q180V Scope caused unreasonably dangerous side effects, in that it allowed for microbial contamination and the spread of infection from one patient to another, Defendants continued to manufacture, market, promote, advertise, distribute and/or sell their Q180V Scopes to consumers, including the Plaintiff WILLIAM JEFFERSON.

78. Defendants knew or should have known that consumers such as the Plaintiff WILLIAM JEFFERSON would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth herein.

79. Defendants' negligence was the proximate, legally attributable cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, continues to suffer and/or will suffer in the future.

80. As a direct and proximate result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including but not limited to, severe and

personal injuries which are permanent and lasting in nature, physical pain and mental anguish and diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

81. If not for Defendants' acts and omissions, described herein, including but not limited to manufacturing, marketing and selling defective Q180V Scopes that retain bacteria to medical facilities to be used in invasive procedures and/or failing to provide adequate and appropriate manufacturers' instructions and/or reprocessing instructions to these same facilities, Plaintiff WILLIAM JEFFERSON would not have sustained a life-threatening infection.

82. It was foreseeable to each and every Defendant that their acts and omissions, including but not limited to manufacturing, marketing and selling defective Q180V Scopes that retain bacteria to medical facilities to be used in invasive procedures and/or failing to provide adequate and appropriate manufacturers' instructions and/or reprocessing instructions to these same facilities, would harm patients undergoing ERCP procedures in which said Q180V Scopes were used.

83. As a result of Defendants' foregoing acts and omissions, Plaintiff requires and/or will require additional health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

84. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS (STRICT PRODUCTS LIABILITY)

85. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 84, with the same force and effect as if more fully set forth herein.

86. At all times herein mentioned, each and every Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and/or distributed the Q180V Scope that was used in the ERCP procedure performed on the Plaintiff, WILLIAM JEFFERSON.

87. The Q180V Scope used in the ERCP procedure performed on the Plaintiff, WILLIAM JEFFERSON, was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, promoted, labeled and marketed by the Defendants.

88. The Q180V Scope used in the ERCP procedure performed on the Plaintiff, WILLIAM JEFFERSON, had not been materially altered or modified prior to its use in the ERCP procedure performed on Plaintiff, WILLIAM JEFFERSON.

89. At all relevant times, the Q180V Scope used in the ERCP procedure performed on the Plaintiff, WILLIAM JEFFERSON, was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff WILLIAM JEFFERSON.

90. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and/or distributed by each and every Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks, including but not limited to the risk of microbial contamination and the spread of infection from one patient to another, exceeded the benefits associated with the design or formulation of the Q180V Scope.

91. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by Defendants was defective in design and/or

formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous due to, among other things, its increased risk of microbial contamination and the spread of infection from one patient to another, and it was more dangerous than an ordinary consumer would expect.

92. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by Defendants was defective in design or formulation in that it was not reasonably fit, suitable, or safe for its intended purpose in that the design of Defendants' Q180V Scope caused it to trap contaminants and rendered it unreasonably difficult to effectively reprocess, which led to the spread of infections from one patient to another.

93. At all times herein mentioned, the Q180V Scope was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided and/or directed by the Defendants.

94. Defendants knew, or should have known, that at all times herein mentioned the Q180V Scope was in a defective condition, in that it allowed for microbial contamination and the spread of infection from one patient to another patient, and was and is inherently dangerous and unsafe.

95. The defective condition of the Q180V Scope that was used in the ERCP performed on the Plaintiff, WILLIAM JEFFERSON was the direct and proximate cause of Plaintiff's life threating injury set forth herein.

96. At the time of the Plaintiff's exposure to the Q180V Scope, the Q180V Scope was being used for the purposes and in a manner normally intended.

97. Defendants with this knowledge voluntarily designed and/or continued with the design of the Q180V Scope in a dangerous condition for use by the public, and in particular the Plaintiff WILLIAM JEFFERSON.

98. If not for the dangerously defective condition and/or design of the Q180V Scope, Plaintiff WILLIAM JEFFERSON, would not have been harmed and would not have endured a life-threating infection and any and all of its sequelae.

99. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

100. Defendants created a product unreasonably dangerous for its normal, intended use in that the Q180V Scope, among other things, allowed for microbial contamination and the spread of infection from one patient to another patient.

101. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by each and every Defendant was manufactured defectively in that the Q180V Scope left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

102. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by each and every Defendant reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Q180V Scope was manufactured.

103. Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff WILLIAM JEFFERSON in

particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff WILLIAM JEFFERSON.

104. The Plaintiff and/or his healthcare providers could not, by the exercise of reasonable care, have discovered the Q180V Scope's defects herein mentioned and perceived its danger.

105. The Q180V Scope created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the Q180V Scope and/or its reprocessing instructions created a risk of serious and dangerous side effects including microbial contamination and the spread of infection from one patient to another, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

106. The Q180V Scope, created, designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by each and every Defendant was defective due to inadequate warnings and/or inadequate testing.

107. The Q180V Scope created designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by each and every Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including but not limited to microbial contamination and the spread of infection from one patient to another, as well as other severe and permanent health consequences from the Q180V Scope, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, the Q180V Scope.

108. The Q180V Scope created designed, researched, manufactured, tested, advertised, promoted, marketed, labeled, sold and distributed by each and every Defendant was defective due to inadequate warnings because, after Defendants knew or should have known of the risks of serious side effects, including but not limited to microbial contamination and the spread of infection from one patient to another, as well as other severe and permanent health consequences from the Q180V Scope, they failed to provide adequate warnings to users or consumers of the product regarding the appropriate method for reprocessing, cleaning and/or sanitizing the Q180V Scope

109. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the designing, manufacturing, marketing, promoting, advertising, labeling, distributing, and selling of a defective product, the Q180V Scope.

110. The design defects, manufacturing defects and/or inadequate warnings associated with the Q180V Scope were the direct and proximate cause of Plaintiff's injuries as set forth herein.

111. It was foreseeable to each and every Defendant that their design, manufacture, promotion, marketing, adverting, labeling, sale and/or distribution of a defective product and/or a product with inadequate warnings, such as the Q180V Scope, would cause serious bodily harm to patients who underwent invasive procedures in which these defective products were used.

112. Said defects in Defendants' Q180V Scope were a substantial factor in causing Plaintiff WILLIAM JEFFERSON's injuries.

113. But for the defects in Defendants' Q180V as set forth herein, Plaintiff WILLIAM JEFFERSON would not have contracted a life-threating infection which required extensive medical care and hospitalization.

114. Defendants' Q180V Scope, as designed, posed a substantial and inevitable likelihood of harm, and it was possible to design such a product in a safer manner (such as that of earlier duodenoscope models).

115. Plaintiff WILLIAM JEFFERSON's above-stated infection that resulted from the defective Q180V Scope, caused him to sustain severe personal injuries, pain, suffering, and emotional distress, as well as to incur substantial medical expenses.

116. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

117. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY—FAILURE TO WARN)

118. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 117, with the same force and effect as if more fully set forth herein.

119. At all relevant times, Defendants had an ongoing duty to advise the Plaintiff, his healthcare providers and the medical community and the general public in a timely manner of risks associated with their Q180V Scope, including but not limited to the risk of microbial contamination and the spread of infection from one patient to another patient.

120. However, Defendants failed to fulfill the above-stated duty for several years after learning definitively of these risks in that they, among other things, failed to inform the Plaintiff, his healthcare providers and the medical community of the risk of microbial contamination and the spread of infection from one patient to another patient associated with their Q180V Scopes,

and failed to adequately and appropriately inform healthcare providers of the accurate and appropriate method for reprocessing their Q180V Scopes.

121. Defendants' failure to promptly and adequately warn the Plaintiff, his healthcare providers and the medical community and general public of the risks associated with their Q180V Scopes prevented Plaintiff, WILLIAM JEFFERSON, and his healthcare providers from making an informed choice regarding the use of this instrument in his procedure.

122. Upon information and belief, Plaintiff's healthcare providers would not have used the Q180V Scope in his procedure had they known of the risks associated with the Q180V Scopes

123. Upon information and belief, had Plaintiff's healthcare providers known of the risks associated with the Q180V Scopes, they would have warned the Plaintiff of said risks.

124. Plaintiff would not have allowed his physician to use the Q180V Scope in his procedure had he known of the risks associated with the Q180V Scope.

125. Defendants' failure to promptly and adequately warn the Plaintiff, his healthcare providers and the medical community of the risks associated with the Q180V Scope also prevented Plaintiff's hospital from making an informed choice regarding the purchase of this instrument, as well as regarding the reprocessing of the instrument.

126. Upon information and belief, had Defendants promptly and adequately warned of the aforementioned risks, such warnings would have been heeded by Plaintiff's hospital, in that the hospital would have changed the manner in which it selected the Q180V Scope for use by its physicians, including but not limited to seeking safer duodenoscope models and/or reevaluating their reprocessing protocol for the Q180V Scope.

127. Had Plaintiff been warned of the aforementioned risks, she would have sought alternate treatment that did not carry the risk of life-threatening infections, and thus would have avoided the aforesaid injuries.

128. Defendants' failure to warn is the direct and proximate cause of Plaintiff WILLIAM JEFFERSON's injuries.

129. Due to Defendants' failure to warn of the risks of their Q180V Scope, Defendants are strictly liable to Plaintiff WILLIAM JEFFERSON.

130. Due to Defendants' failure to warn of the risks of their Q180V Scope, Plaintiff, WILLIAM JEFFERSON, sustained severe personal injuries, pain, suffering, and emotional distress, as well as to incur substantial medical expenses.

131. Plaintiff's above-stated infection, that resulted from Defendants' failure to warn of the risks associated with their Q180V Scope, caused Plaintiff, WILLIAM JEFFERSON to sustain severe personal injuries, pain, suffering, and emotional distress, as well as to incur substantial medical expenses.

132. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

133. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

134. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 133, with the same force and effect as if more fully set forth herein.

135. Each and every Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, his treating physicians, and healthcare providers, the FDA, and/or the the public in general, that said product, the Q180V Scope, had been tested and was found to be safe and effective for use during ERCP procedures, in that it did not cause microbial contamination and/or the spread of infection from one patient to another.

136. Each and every Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, his treating physicians, and healthcare providers, the FDA, and/or the the public in general, that the Q180V Scope was superior to other duodenoscopes on the market because of its closed-channel design.

137. Each and every Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, his treating physicians, and healthcare providers, the FDA, and/or the the public in general, that the closed-channel design of the Q180V Scope prevented the elevator wire channel from exposure to microbial contamination, thereby reducing the risk of the spread of infection.

138. Each and every Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, his treating physicians, and healthcare providers, the FDA, and/or the the public in general, that the closed-channel design of the Q180V Scope

prevented infectious material from entering the scope, thereby, reducing the risk of the spread of infection.

139. These representations made by each and every Defendant were made by means of media advertisement, internet advertisements, press releases, sales literature, presentations, advertising campaigns, print ads, magazine ads and/or additional commercial media, at all times Defendants marketed their Q180V Scopes.

140. These representations made by each and every Defendant were, in fact, false.

141. When said representations were made by each and every Defendant, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

142. These representations were made by each and every Defendant with the intent of defrauding and deceiving the Plaintiff, WILLIAM JEFFERSON, his healthcare providers, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, and/or use the Q180V Scope, all of which evinced a callous, reckless, willful, wanton and/or depraved indifference to the health, safety and welfare of the Plaintiff herein.

143. At the time the aforesaid representations were made by each and every Defendant and, at the time the Q180V Scope was used during Plaintiff's ERCP procedure, the Plaintiff and/or healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

144. In reliance upon said representations, the Plaintiff and/or his healthcare providers were induced to and did use the Q180V Scope, thereby causing the Plaintiff WILLIAM

JEFFERSON to sustain severe and permanent personal injuries, including but not limited to a life-threatening antibiotic resistant infection, and/or to be at an increased risk of sustaining severe and permanent personal injuries in the future.

145. Each and every Defendant knew and was aware or should have been aware that the Q180V Scope had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

146. Each and every Defendant knew or should have known that the Q180V Scope had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

147. Each and every Defendant brought the Q180V Scope to the market, and acted fraudulently, willfully, wantonly and maliciously to the detriment of the Plaintiff.

148. As a result of Defendants' fraudulent misrepresentations, Plaintiff WILLIAM JEFFERSON was caused to suffer from a life-threatening infection as well as other permanent severe personal injuries, pain, suffering, and emotional distress.

149. As a result of the foregoing acts and omissions by each and every Defendant, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services

150. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

151. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 150, with the same force and effect as if more fully set forth herein.

152. At all times during the course of dealing between each and every Defendant and Plaintiff, Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the serious and grave health risks that could occur by virtue of use of the Q180V Scope for its intended purpose, including but not limited to life-threatening infections.

153. Each and every Defendant knew or was reckless in not knowing that its representations were false.

154. In representations to Plaintiff, and/or his healthcare providers, and/or the FDA, made by means of media advertisement, internet advertisements, press releases, sales literature, presentations, advertising campaigns, print ads, magazine ads, additional commercial media, and/or correspondence, each and every Defendant fraudulently concealed and intentionally omitted the following material information:

(a) that the Q180V Scope was not as safe as other duodenoscopes, such that it increased the risk of microbial contamination and the spread of infection from one patient to another;

(b) that the risks of adverse events with the Q180V Scope, such as microbial contamination and the spread of infection from one patient to another, were higher than with other duodenoscopes;

(c) that the risks of adverse events with the Q180V Scope were not adequately tested and/or known by each and every Defendant;

(d) that each and every Defendant was aware of dangers in the Q180V Scope that were in addition to and above and beyond those associated with other duodenoscopes;

(e) that the Q180V Scopes were defective, and caused dangerous side effects, including but not limited to infections, as well as other severe and permanent health consequences, in a much higher rate than other duodenoscopes;

(f) that the use of Q180V Scopes resulted in dangerous side effects, including but not limited to microbial contamination and the spread of infection from one patient to another,

(g) that the Q180V Scope was manufactured, marketed, produced, sold and distributed negligently;

(h) that the Q180V Scope was manufactured, marketed, produced, sold and distributed defectively;

(i) that the Q180V Scope was manufactured, marketed, produced, sold and distributed improperly;

(j) that the Q180V Scope's reprocessing instructions were inadequate in that they did not instruct, direct and/or otherwise allow for proper and/or adequate cleaning and sanitizing of the Q180V Scope;

(k) that the Q180V Scope's reprocessing instructions did not prevent the spread of infection, but in fact increased the risk of the spread of infection;

(l) that the Q180V Scope was designed negligently;

(m) that the Q180V Scope was designed defectively; and

(n) that the Q180V Scope was designed improperly.

155. Each and every Defendant was under a duty to disclose to Plaintiff, Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Q180V Scope, including but not limited to the heightened risks of infections associated with its use.

156. Each and every Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Q180V Scope, including Plaintiff, in particular.

157. Plaintiff and/or his treating healthcare providers were unaware of the defective nature of the Q180V Scope and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Q180V Scope, including Plaintiff, in particular, because this information was in the custody, possession and control of the each and every Defendant.

158. Each and every Defendant's concealment and omissions of material facts concerning, *inter alia*, the safety of the Q180V Scope was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and his healthcare providers into reliance, continued use of the Q180V Scope, and actions thereon, and to cause them to purchase and/or use the Q180V Scope.

159. Each and every Defendant knew that Plaintiff, his healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Q180V Scope, as set forth herein.

160. Plaintiff, as well as his healthcare providers reasonably relied on facts revealed which recklessly, willfully, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

161. Upon information and belief, had the severe health risks associated with the Q180V Scope, as outlined herein, been properly and/or adequately disclosed, Plaintiff's healthcare providers would not have purchased and/or used the Q180V Scope.

162. Upon information and belief, had had the severe health risks associated with the Q180V Scope, as outlined herein, been properly and/or adequately disclosed, Plaintiff's healthcare providers would have warned the Plaintiff of said risks.

163. Had the severe health risks associated with the Q180V Scope, as outlined herein, been properly and/or adequately disclosed, Plaintiff would not have allowed the Q180V Scope to be used in his surgery.

164. As a result of Defendants' fraudulent concealments, Plaintiff WILLIAM JEFFERSON was caused to suffer from a life-threatening infection as well as other permanent severe personal injuries, pain, suffering, and emotional distress.

165. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

166. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

167. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 166, with the same force and effect as if more fully set forth herein.

168. Each and every Defendant had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that the Q180V Scope had been tested and found to be safe and effective for its intended use.

169. Each and every Defendant had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general any and all side effects and/or risks associated with the Q180V Scope.

170. Representations made by each and every Defendant regarding the testing and/or safety of the Q180V Scope were, in fact, false.

171. These representations made by each and every Defendant were made by means of media advertisement, internet advertisements, press releases, sales literature, presentations, advertising campaigns, print ads, magazine ads and/or additional commercial media, at all times Defendants marketed their Q180V Scopes.

172. Each and every Defendant failed to exercise ordinary care in the representations they made regarding the safety of the Q180V Scope, while involved in its design, manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that each and every Defendant negligently misrepresented the Q180V Scope's high risk of unreasonable, dangerous side effects, including but not limited to microbial contamination and the spread of infection from one patient to another.

173. Each and every Defendant breached its duty in misrepresenting the Q180V Scope's serious side effects, including but not limited to microbial contamination and the spread of infection from one patient to another, to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

174. Each and every Defendant knew and/or should have known that the Q180V Scope had been insufficiently tested and/or had not been tested, that it lacked adequate and/or accurate warnings, that its reprocessing instructions were inadequate and inaccurate, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks of severe and grave health consequences, including but not limited to microbial contamination and the spread of infection from one patient to another.

175. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including a life-threatening infection, severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish and diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of infection recurrence.

176. As a result of Defendants' negligent misrepresentations, Plaintiff WILLIAM JEFFERSON was caused to suffer from a life-threatening infection as well as other permanent severe personal injuries, pain, suffering, and emotional distress.

177. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

178. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

179. Plaintiffs repeat, reiterate, and reallege each and every allegation in Paragraphs 1 through 178, with the same force and effect as if more fully set forth herein.

180. Each and every Defendant conducted research using the Q180V Scope as part of their research.

181. As a result of Defendants' research and testing, or lack thereof, each and every Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, WILLIAM JEFFERSON, Plaintiff's doctors, hospitals,

healthcare professionals, and/or the FDA that the Q180V Scope was safe and effective for its intended use in ERCP procedures.

182. As a result of each and every Defendant's research and testing, or lack thereof, each and every Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

183. Each and every Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

184. The information distributed to the public, the FDA, and the Plaintiff by each and every Defendant, including but not limited to reports, press releases, advertising campaigns, print ads, magazine ads, and all other commercial media contained material representations of fact and/or omissions.

185. The information distributed to the public, the FDA, and the Plaintiff by each and every Defendant intentionally included representations that the Q180V Scope was safe and effective for its intended use as a duodenoscope.

186. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that the Q180V Scope carried the same risks, hazards, and/or dangers as other duodenoscopes on the market.

187. The information distributed to the public, the FDA, and the Plaintiff, by each and every Defendant intentionally included false representations that the Q180V Scope was not injurious to the health and/or safety of its intended users.

188. The information distributed to the public, the FDA, and Plaintiff by each and every Defendant intentionally included representations that the Q180V Scopes were better alternatives

for use in ERCP procedures than other duodenoscopes, thereby encouraging the use of Q180V scopes over other duodenoscopes.

189. The information distributed to the public, the FDA, Plaintiff, and Plaintiff's healthcare providers by each and every Defendant intentionally included false representations that the Q180V Scope was not injurious to the health and/or safety of its intended use as other duodenoscopes.

190. These representations were all false and misleading.

191. Upon information and belief, each and every Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the Q180V Scope was not safe as other duodenoscopes.

192. Each and every Defendant intentionally made material representations to the FDA and the public, including the medical profession, and Plaintiff, regarding the safety of the Q180V Scope, specifically but not limited to the Q180V Scope not having dangerous and serious health and/or safety concerns.

193. Each and every Defendant intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of the Q180V Scope, specifically but not limited to Q180V Scope being as safe as other duodenoscopes on the market.

194. That it was the purpose of each and every Defendant in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of The Q180V Scope and induce the public, healthcare

professionals, the FDA, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use the Q180V Scope.

195. Each and every Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the Q180V Scope was fit and safe for use as a duodenoscope.

196. Each and every Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the Q180V Scopes was fit and safe for use as duodenoscopes and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other duodenoscopes on the market.

197. Each and every Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Q180V Scope did not present serious health and/or safety risks.

198. Each and every Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Q180V Scope did not present health and/or safety risks greater than other duodenoscopes on the market.

199. That these representations and others made by each and every Defendant were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

200. That these representations and others, made by each and every Defendant, were made with the intention of deceiving and defrauding the Plaintiff, including his respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or

his respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to undergo ERCP using a Q180V Scope.

201. Each and every Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of the Q180V Scope to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other duodenoscopes.

202. That each and every Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the Q180V Scope by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of the Q180V Scope.

203. Each and every Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as his respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and allow the Q180V Scope to be used on him and/or that Plaintiff's respective healthcare providers would dispense, recommend and/or use the same.

204. Each and every Defendant, through its public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare providers would rely upon the information being disseminated.

205. The Plaintiff and/or his respective healthcare providers did in fact rely on and believe each and every Defendant's representations to be true at the time they were made and relied

upon the representations as well as the superior knowledge of duodenoscopes and were thereby induced to purchase, use and rely on the Q180V Scope.

206. At the time the representations were made, the Plaintiff and/or his respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of the Q180V Scope, including the fact that it increased the risk of microbial contamination and the spread of infection from one patient to another.

207. The Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of each and every Defendant, nor could the Plaintiff with reasonable diligence have discovered the true facts.

208. Each and every Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

209. As a result of Defendants' fraud and deceit, Plaintiff WILLIAM JEFFERSON was caused to suffer from a life-threatening infection as well as other permanent severe personal injuries, pain, suffering, and emotional distress.

210. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

211. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOSS OF CONSORTIUM)

212. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint

in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

213. Plaintiff CARMAYNE JEFFERSON is and was at all relevant times the lawful spouse of Plaintiff WILLIAM JEFFERSON and as such, was entitled to the comfort, enjoyment, society and services of her spouse.

214. As a direct and proximate result of the foregoing, Plaintiff CARMAYNE JEFFERSON was deprived of the comfort and enjoyment of the services and society of her spouse Plaintiff WILLIAM JEFFERSON and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiff CARMAYNE JEFFERSON's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual damages from the Defendants as alleged herein.

215. For the reasons set forth herein, Plaintiff CARMAYNE JEFFERSON suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection.

216. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case may be transferred for trial;

2. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe injuries sustained by Plaintiffs, health care costs, loss of wages and/or earning capacity, and medical monitoring, together with interest and costs as provided by law;

3. Punitive and/or exemplary damages for the intentional, wanton, willful, fraudulent, reckless, and/or grossly negligent acts of Defendants, who demonstrated a profound disregard and reckless indifference for the health and welfare of the general public and of the Plaintiffs, in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding Plaintiffs reasonable attorneys' fees;

5. Awarding Plaintiffs the cost of these proceedings; and

6. Such other and further relief as this Court deems just and proper.

Dated: February 20, 2018

DOUGLAS & LONDON, P.C.

By: */s/ Virginia E. Anello*
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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

/s/ Virginia E. Anello
VIRGINIA E. ANELLO (VEA-8197)